Amendments To The Claims

The listing of claims will replace all prior versions, and listings, of the claims in the application.

Listing Of Claims:

Claim 1 (Currently Amended) A method for planning a stability study of a pharmaceutical composition comprising: a) selecting a value for a release limit variable for a given specification test; b) selecting a desired length of the shelf-life of said pharmaceutical composition; c) selecting a time at which an analysis of the data for said stability study will be performed; d) selecting time points at which one or more measurements of one or more predetermined pharmaceutical test variables will be performed; e) selecting a number of measurements of said predetermined test variables that will be performed at each of said time points; f) selecting a value for ~~the~~ an expected degradation rate of said pharmaceutical composition over time; g) selecting a value for ~~the~~ an intermediate precision of said measurements; ~~and~~ h) selecting a probability level of at least 90% regarding the level of certainty of the outcome of said stability study, and i) preparing at least one batch of said pharmaceutical composition for use in said stability study based upon the variables selected in steps a) through h).

Claim 2 (Previously presented) The method of claim 1 wherein the selected value of said expected degradation rate is based on previous long-term stability studies.

Claim 3 (Previously presented) The method of claim 1, further comprising calculating the shelf-life specification limits of said pharmaceutical composition based upon the variables selected in steps a) through h).

Claim 4 (Previously presented) The method of claim 3 further comprising optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation.

Claim 5 (Previously presented) The method of claim 3 wherein the specification test limits are re-calculated by substituting in actual data obtained during said stability study for one or more of the variables selected in steps a) through h).

Claim 6 (Previously presented) The method of claim 5 further comprising optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation.

Claim 7 (Previously presented) The method of claim 6 wherein said probability level regarding the level of certainty is at least 95%.

Claim 8 (Cancelled)

Claim 9 (Previously presented) The method of claim 1 wherein said probability level is 95%.

Claim 10 (Previously presented) The method of claim 1 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition in alternate formulations.

Claim 11 (Previously presented) The method of claim 1 wherein the selected value of said expected degradation rate is based on previous accelerated stability studies of said pharmaceutical composition.

Claim 12 (Previously presented) The method of claim 11 wherein the selected value is based on accelerated stability results that are temperature corrected by the Arrhenius formula.

Claim 13 (Previously presented) The method of claim 1 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

Claim 14 (Previously presented) The method of claim 1 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous accelerated stability studies of said pharmaceutical composition.

Claim 15 (Previously presented) The method of claim 1 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from conducting a stability study

of said pharmaceutical composition.

Claim 16 (Previously presented) The method of claim 1 wherein the selected value of said expected degradation rate is based on conducting a stability study of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

Claim 17 (Previously presented) The method of claim 1 wherein the time points for measurement of the variables selected in steps a) through h) are at 0, 3, 6, 9, and 12 months after start of the stability study of said pharmaceutical composition.

Claim 18 (Previously presented) The method of claim 1 wherein the shelf-life specification limits of said pharmaceutical composition is calculated utilizing the Allen Formula.

Claim 19 (Previously presented) The method of claim 1 wherein the shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the probability level of said pharmaceutical composition satisfying its specification tests is at least 95%.

Claim 20 (Currently Amended) The method of claim 1 wherein said pharmaceutical composition is administered through an oral administration of a pharmaceutical formulation ~~such as a tablet~~.

Claim 21 (Cancelled)

Claim 22 (Previously presented) The method of claim 20 wherein the packaging for said pharmaceutical formulation varies.

Claim 23 (Currently Amended) The method of claim 20 wherein the dosage strength of an active ingredient in said ~~tablet~~ pharmaceutical formulation varies.

Claim 24 (Currently Amended) A method of determining shelf-life specifications of pharmaceutical composition, comprising: a) selecting a value for a release limit variable for a

given specification test; b) selecting a desired length of the shelf-life of said pharmaceutical composition; c) selecting a time at which an interim analysis will be performed; d) selecting time points at which one or more measurements of one or more predetermined pharmaceutical test variables will be performed; e) selecting a number of measurements of said predetermined test variables that will be performed at each of said time points; f) selecting a value for ~~the~~ an expected degradation rate of said pharmaceutical composition over time; g) selecting a value for ~~the~~ an intermediate precision of said measurements; and h) selecting a probability level regarding the level of certainty of the outcome of said stability study; ~~and~~ i) calculating the shelf-life specification limits of said pharmaceutical composition based upon the variables selected in steps a) through h), and i) preparing at least one batch of said pharmaceutical composition based upon the shelf-life specifications calculated in step i).

Claim 25 (Previously presented) The method of claim 24 wherein said probability level regarding the level of certainty is at least 90%.

Claim 26 (Previously presented) The method of claim 24 further comprising optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation.

Claim 27 (Previously presented) The method of claim 24 wherein the selected value of said expected degradation rate is based on previous long-term stability studies.

Claim 28 (Previously presented) The method of claim 24 wherein the specification test limits are re-calculated by substituting in actual data obtained during said stability study for one or more of the variables selected in steps a) through h).

Claim 29 (Previously presented) The method of claim 24 wherein said probability level is at least 95%.

Claim 30 (Previously presented) The method of claim 24 wherein said probability level is 99%.

Claim 31 (Previously presented) The method of claim 24 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said

pharmaceutical composition in alternate formulations.

Claim 32 (Previously presented) The method of claim 24 wherein the selected value of said expected degradation rate is based on previous accelerated stability studies of said pharmaceutical composition.

Claim 33 (Previously presented) The method of claim 24 wherein the selected value is based on accelerated stability results that are temperature corrected by the Arrhenius formula.

Claim 34 (Previously presented) The method of claim 24 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

Claim 35 (Previously presented) The method of claim 24 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous accelerated stability studies of said pharmaceutical composition.

Claim 36 (Previously presented) The method of claim 24 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from conducting a stability study of said pharmaceutical composition.

Claim 37 (Previously presented) The method of claim 24 wherein the selected value of said expected degradation rate is based on conducting a stability study of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

Claim 38 (Previously presented) The method of claim 24 wherein the time points for measurement of the variables selected in steps a) through h) are at 0, 3, 6, 9, and 12 months after start of the stability study of said pharmaceutical composition.

Claim 39 (Previously presented) The method of claim 24 wherein the shelf-life specification

limits of said pharmaceutical composition is calculated utilizing the Allen Formula.

Claim 40 (Previously presented) The method of claim 24 wherein the shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the probability level of said pharmaceutical composition satisfying its specification tests is at least 90%.

Claim 41 (Currently Amended) The method of claim 24 wherein said pharmaceutical composition is administered through an oral administration of a pharmaceutical formulation ~~such as a tablet~~.

Claim 42 (Cancelled)

Claim 43 (Previously presented) The method of claim 41 wherein the packaging for said pharmaceutical formulation varies.

Claim 44 (Currently amended) The method of claim 41 wherein the dosage strength of an active ingredient in said ~~tablet~~ pharmaceutical formulation varies.

Claim 45 (Currently Amended) A method for planning and conducting a stability study of a pharmaceutical composition comprising: a) selecting a value for a release limit variable for a given specification test; b) selecting a desired length of the shelf-life of said pharmaceutical composition; c) selecting a time at which an interim analysis will be performed; d) selecting time points at which one or more measurements of one or more predetermined pharmaceutical test variables will be performed; e) selecting a number of measurements of said predetermined test variables that will be performed at each of said time points; f) selecting a value for ~~the~~ an expected degradation rate of said pharmaceutical composition over time; g) selecting a value for ~~the~~ an intermediate precision of said measurements; and h) selecting a probability level regarding the level of certainty of the outcome of said stability study; i) calculating the shelf-life specification limits of said pharmaceutical composition

based upon the variables selected in steps a) through h); j) optimizing the variables selected in steps a) through h) by changing one or more of said variables as a function of said calculation; and k) conducting ~~a~~ said stability study for said pharmaceutical composition based on said optimized values selected for said pharmaceutical composition.

Claim 46 (Previously presented) The method of claim 45 wherein the specification test limits are re-calculated by substituting in actual data obtained during said stability study for one or more of the variables selected in steps a) through h).

Claim 47 (Previously presented)The method of claim 45 wherein said probability level regarding the level of certainty is at least 90%.

Claim 48 (Previously presented) The method of claim 45 wherein the shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the probability level of said pharmaceutical composition satisfying its specification tests is at least 95%.

Claim 49 (Previously presented) The method of claim 45 wherein the selected value of said expected degradation rate is based on previous long-term stability studies.

Claim 50 (Previously presented) The method of claim 45 wherein said probability level is at least 95%.

Claim 51 (Previously presented) The method of claim 45 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition in alternate formulations.

Claim 52 (Previously presented) The method of claim 45 wherein the selected value of said expected degradation rate is based on previous accelerated stability studies of said

pharmaceutical composition.

Claim 53 (Previously presented) The method of claim 52 wherein the selected value is based on accelerated stability results that are temperature corrected by the Arrhenius formula.

Claim 54 (Previously presented) The method of claim 45 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

Claim 55 (Previously presented) The method of claim 45 wherein the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous accelerated stability studies of said pharmaceutical composition.

Claim 56 (Previously presented) The method of claim 45 wherein the selected value of said expected degradation rate is based on previous long-term stability studies of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from conducting a stability study of said pharmaceutical composition.

Claim 57 (Previously presented) The method of claim 45 wherein the selected value of said expected degradation rate is based on conducting a stability study of said pharmaceutical composition while the selected value of said intermediate precision of the analysis of said pharmaceutical composition is determined from previous long-term stability studies of said pharmaceutical composition.

Claim 58 (Previously presented) The method of claim 45 wherein the time points for measurement of the variables selected in steps a) through h) are at 0, 3, 6, 9, and 12 months after start of the stability study of said pharmaceutical composition.

Claim 59 (Previously presented) The method of claim 45 wherein the probable shelf-life specification limits of said pharmaceutical composition are calculated utilizing the Allen Formula such that the probability level of said pharmaceutical composition satisfying its specification tests is at least 95%.

Claim 60 (Currently Amended) The method of claim 45 wherein said pharmaceutical composition is administered through an oral administration of a pharmaceutical formulation ~~such as a tablet~~.

Claim 61 (Cancelled)

Claim 62 (Previously presented) The method of claim 60 wherein the packaging for said pharmaceutical formulation varies.

Claim 63 (Currently Amended) The method of claim 60 wherein the dosage strength of an active ingredient in said ~~tablet~~ pharmaceutical formulation ~~vanes~~. varies.

Claim 64 (Previously presented) The method of claim 1 wherein in said analysis is an interim analysis.

Claim 65 (Previously presented) The method of claim 64 wherein in said interim analysis is performed at least once.

Claim 66 (Previously presented) The method of claim 1 further comprising selecting the number of batches of said pharmaceutical composition to be prepared is determined.

Claim 67 (Cancelled)

Claim 68 (Currently Amended) The method of claim ~~67~~ 1 wherein at least three batches of said pharmaceutical composition are prepared for testing in said stability study.

Claim 69 (Previously presented) The method of claim 68 wherein said at least one batch of said pharmaceutical composition is tested for degradation.

Claim 70 (Previously presented) The method of claim 24 further comprising selecting the number of batches of said pharmaceutical composition to be prepared is determined.

Claim 71 (Cancelled)

Claim 72 (Currently Amended) The method of claim ~~71~~ 24 wherein at least three batches of said pharmaceutical composition are prepared for testing in said stability study.

Claim 73 (Previously presented) The method of claim 72 wherein said at least one batch of said pharmaceutical composition is tested for degradation.

Claim 74 (Previously presented) The method of claim 45 further comprising selecting the number of batches of said pharmaceutical composition to be prepared is determined.

Claim 75 (Previously presented) The method of claim 45 wherein at least one batch of said pharmaceutical composition is prepared.

Claim 76 (Previously presented) The method of claim 75 wherein at least three batches of said pharmaceutical composition are prepared for testing in said stability study.

Claim 77 (Previously presented) The method of claim 76 wherein said at least one batch of

said pharmaceutical composition is tested for degradation.

Claim 78 (Previously presented) The method of claim 24 wherein in said analysis is an interim analysis.

Claim 79 (Previously presented) The method of claim 78 wherein in said interim analysis is performed at least once.

Claim 80 (Previously presented) The method of claim 45 wherein in said analysis is an interim analysis.

Claim 81 (Previously presented) The method of claim 80 wherein in said interim analysis is performed at least once.